

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
CIVIL NO. 3:17-CV-37

UNITED STATES OF AMERICA *ex rel.*
TARYN HARTNETT, and DANA
SHOCHED,

Plaintiff,

v.

PHYSICIANS CHOICE LABORATORY
SERVICES, DOUGLAS SMITH, PHILIP
MCHUGH AND MANOJ KUMAR,

Defendants.

**MEMORANDUM IN SUPPORT OF THE
UNITED STATES' MOTION FOR
PARTIAL SUMMARY JUDGMENT AS
TO DEFENDANT MCHUGH**

Defendant Philip McHugh directed and participated in three distinct kickback schemes to induce the referral of urine drug testing (“UDT”) samples, including those from Medicare beneficiaries, to Physicians Choice Laboratory Services (“PCLS”), a toxicology lab in which McHugh had a significant ownership interest in and from which he personally received roughly \$27.5 million in distributions. These three kickback schemes—each involving two doctors—operated in three separate ways to induce UDT referrals to PCLS: (1) McHugh and his associate Manoj Kumar offered and/or paid expenses to Drs. Nickels and Johnson for the set-up of in-office analyzer labs; (2) McHugh and Kumar made loans to Drs. Florete and Jayachandran; and (3) McHugh arranged for Kumar to be paid volume-based commissions on referrals of two doctors for whom Kumar also provided management services, Drs. Shah and Masimore. And not only was this remuneration offered and/or given with the intent to induce the referral of UDT samples to PCLS, but each kickback scheme was successful in doing so: the claims data shows a tight temporal nexus between the beginning of the kickback negotiations in each scheme and the

inception of the referral of samples. PCLS billed Medicare for these referrals, and as claims tainted by kickbacks are *per se* false claims, the United States seeks entry of judgment against McHugh, finding him liable under the False Claims Act (Counts I and II), and awarding treble damages and assessing civil penalties as compensation for the loss to the Medicare program.

LEGAL FRAMEWORK OF THE FCA AND AKS

The Anti-Kickback Statute (“AKS”) specifically forbids any person or entity from knowingly and willfully offering, paying, soliciting, or receiving remuneration to influence the referral of items or services reimbursable by a federal healthcare program. 42 U.S.C. § 1320a–7b(b). A violation of the False Claims Act, 31 U.S.C. §§ 3729-3733 (“FCA”), occurs when a person “knowingly presents, or *causes* to be presented, a false or fraudulent claim for payment or approval” by the United States, 31 U.S.C. § 3729(a)(1)(A) (emphasis added), or, “knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim...” *Id.* at §3729(a)(1)(B). “An AKS violation resulting in a federal health care payment automatically constitutes a false claim under FCA.” *U.S. ex rel. Hartnett v. Physicians Choice Laboratory Services, LLC*, 2020 WL 571322, at *3 (W.D.N.C. Feb. 5, 2020).

BACKGROUND FACTS

I. PCLS AND ITS OWNERS

PCLS, now defunct, was a diagnostic laboratory specializing in toxicology services formed in January 2009 by McHugh and Defendant Doug Smith (JW 42:5-14).¹ Initially, McHugh had the titles of President and CEO, and ran the sales and marketing department (PM 36:21-24; AC 27:10-21). Smith, also a President, was the “silent investor” (JM 58:8-17). Marcus Sowinski became an

¹ Deposition excerpts are contained in Exhibits 65 through 82. For simplicity and specificity, the Government cites these excerpts using the abbreviation of the witnesses’ first and last name, *i.e.* JW is Joe Wiegand, found at Ex. 80.

owner in late 2009, took the title of President, and served as the Company's COO (MS 14:12-14). According to McHugh, the original ownership percentages in PCLS were approximately 50% for Smith, 25% for McHugh, and 20% for Sowinski (PM 36:5-20). In 2011, Joe Wiegel, previously a consultant to PCLS, joined the Company at an "executive level position," and initially obtained a 4% ownership interest in the Company, which later grew to between 6 and 10 percent (JW 13:16-14:3). Wiegel was named CEO in or around 2014 as PCLS prepared itself for sale (JW 15:5-7, 17:4-21; AC 28:1-29:2). Around this time, McHugh, Smith and Sowinski took a step back from day-to-day management but continued to remain active Board members (JW 18:3-8; AC 36:4-37:4).

PCLS' primary business line was quantitative/confirmation urine drug testing (JW 42:5-14). A patient's urine drug sample can be tested in two general ways: qualitatively or quantitatively. Qualitative testing, also called screening or presumptive testing, is used when medically necessary to determine the presence or absence of drugs in a patient sample; results are typically expressed as negative or positive (Ex.1, Report of P. Gulur, ¶1). There are certain limitations to qualitative testing, which may prompt practitioners to seek quantitative testing, when medically necessary (*Id.*). Quantitative or confirmation testing may be used to determine the concentration or amount of a specific medication, illicit substance, or metabolite in the patient sample (Ex. 1, ¶2; JT 15:2-9). In short, qualitative testing tends to be simpler, easier, and done at the point of care, while quantitative testing is more complex, more detailed, and often done at a confirmation lab (JN 16:2-17:17).

Neither McHugh, Smith, nor Sowinski had any experience working in or operating a diagnostic laboratory (PM 38:5-39:7, 52:24-53:1-5; AC 16:6-10). Despite this, PCLS grew quickly. For example, Mark Roth (the former VP of Operations) testified that in 2009, the lab was

testing between zero and 1,000 samples a month, but was testing between 20,000 to 40,000 samples a month by 2013 (MR 10:20-24; 11:1-4). At its largest, Roth estimated the Company employed between 400-500 employees (MR 17:9-12). From 2009 through 2015, PCLS billed the Medicare Program under Part B (medical insurance), and the Medicare Program in turn paid PCLS at least \$125,073,745 for tests, primarily UDTs, performed on Medicare beneficiary samples (Ex. 18, Report of E. Hines, ¶16). PCLS marketed its services nationally through a team of 1099 channel partners (PCLS' term for independent contractors), and 1099 and W2 sales representatives (AC 25:21-22; JM 37:16-21; PM 137:17-20, MK 56:18-23). The 1099 channel partners or sales reps were paid commissions based on reimbursement for samples referred from their accounts (JT 11:19-21), and W2 sales reps were paid a salary and a commission off collections (CK 17:10-23).

II. THE LOSS OF UOFL BUSINESS PRIOR TO THE KICKBACK SCHEMES

In November 2010, PCLS entered into an arrangement with Universal Oral Fluids Laboratory ("UOFL"), a laboratory specializing in saliva drug testing ("UOFL") (JT 16:14-24; Ex. 2). UOFL was owned and operated by William ("Bill") Hughes (JT 13:24-25). At the time, UOFL was performing qualitative testing and Hughes was looking for a laboratory to do confirmation testing on saliva samples UOFL obtained from physicians (JT 14:2-12; 15:10-19).

PCLS sales rep Jeff Thomas arranged a meeting between Hughes and McHugh in Pittsburgh in the fall of 2010 for the purpose of discussing that arrangement, specifically, that UOFL would conduct qualitative tests on patient samples it received from "business" (*i.e.* doctors) it brought on board, and then send the samples to PCLS for confirmation testing (PM 58:2-11; JT 15:20-16:12; 17:14-16; JJ 21:7-24; MR 46:11-24, 47:7-19).² Both labs profited under this

² Thomas left PCLS and went as the COO at UOFL in January 2012, and remained at UOFL until summer of 2014, when the lab shut down following an FBI investigation (JT 36:24-37:5; 38:22-39:4). Thomas cooperated in the investigation and was granted immunity from prosecution.

arrangement—UOFL would bill for the initial qualitative tests and PCLS would bill for the confirmation testing. (JT 16:17-18).

According to Thomas, PCLS was likely making millions from its arrangement with UOFL (JT 22:8-11). However, as UOFL began to develop its own quantitative testing capability to capture the revenue from both the screenings and confirmations—meaning UOFL no longer needed PCLS—the relationship soured and eventually ended around late November 2011. (JT 21:15-22:3; 22:12-25; 31:15-20; JJ 21:19-22:1; 111:20-112:2; JW 63:4-64:5; MR 47:20-48:1). In response, PCLS developed a plan to “go after” UOFL referral sources for confirmation testing (JT 22:16-25). Thomas described the effort to regain business as a “blitz,” which included sales representatives and owners meeting face-to-face or calling on UOFL providers (*i.e.* physicians or physician practices). (JT 23:1-11; JW 54:8-55:1). Eventually, PCLS also sent a letter to providers referring to UOFL, among other things, (1) instructing them to instead refer directly to PCLS for confirmation testing, (2) stating that PCLS was “no longer affiliated with [UOFL],” and (3) that effective November 30, 2011, PCLS would no longer accept referral business from UOFL (JJ 22:14-23:5, Ex. 3).

Importantly, when PCLS was in business with UOFL, McHugh (and others at PLCS) knew that UOFL was paying kickbacks to physicians because he was provided with a form copy of the written agreement between the lab and a referring provider (Ex. 4, 5), and the kickback arrangement was discussed by Hughes, McHugh and Thomas during their 2010 Pittsburgh meeting (JT 18:7-11, 20:5-17; 38:5-14; 49:1-20).³ Specifically, UOFL entered into written agreements with referring physicians whereby it would bill private and federal health care programs for testing, and

³ Additionally, Kumar testified that “word-of-mouth in the community was that [UOFL] used to pay their physicians” (MK 150:14-15).

any amounts paid to UOFL in excess of an agreed-upon threshold would be “paid back” to the referring doctor (JT 18:12-20:4). Hughes was indicted on one count of conspiracy (18 U.S.C. § 371) in relation to this kickback scheme, and has pleaded guilty and awaits sentencing. *See* Docs. 103, 121 in W.D. Pa. Case No. 2:18-cr-46.

Other than the Kumar Compensation Scheme, which began when Kumar initially came to PCLS, the kickback schemes alleged in this case began after PCLS lost UOFL’s business in November 2011—and three of the four doctors involved were former UOFL clients.

ARGUMENT AND AUTHORITIES

I. MCHUGH VIOLATED THE ANTI-KICKBACK STATUTE

To establish a violation of the AKS, the United States must show that: (1) the defendant offered or paid remuneration; (2) one purpose of the remuneration was to induce the recipient to prescribe or recommend goods or services for patients, including federal health care program beneficiaries; and (3) the defendant acted knowingly and willfully. 42 U.S.C. § 1320a-7b(b).

Courts have broadly defined “remuneration,” interpreting it to mean “anything of value.” *U.S. v. Chang*, 2017 WL 10544289, at *7 (C.D. Cal. July 25, 2017) (listing authorities). “Congress’s intent in placing the term “remuneration” in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.” 42 CFR § 1001; 56 Fed.Reg. 35,952, 35,957 (1991). The AKS prohibition applies to “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. §§ 1320a-7b(b)(1), (2). In other words, in addition to the more obvious types of remuneration (*e.g.* cash payments, gifts, free vacations, etc.), the AKS also prohibits less direct forms of remuneration—such as payment on behalf of a provider for services performed by another, or “sham” financial transaction, like cash disguised as a loan or compensation for employment. *U.S.*

ex rel. Bartlett v. Ashcroft, 39 F. Supp. 3d 656, 677 (W.D. Pa. 2014) (“Contrary to Defendants’ assertion, remuneration need not be in the form of a “kickback”; instead, remuneration can include anything of value—and in any form—which is given in return for, or to induce, a referral for federal healthcare services.”)

In the context of the AKS, “induce” means to intend to exercise influence over the reason or judgment of another in an effort to cause the referral of goods or services, and the AKS prohibits any arrangement where *at least one* purpose of the remuneration is to induce referrals. *See United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 460, 468 (D.S.C. 2016) (“[I]n FCA cases involving AKS violations, courts have found scienter where one purpose of the remuneration was to induce referrals.”); *see also U.S. v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (“If the payments were intended to induce the physician to use Cardio-Med’s services, the statute was violated, even if the payments were also intended to compensate for professional services.”); *U.S. v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (rejecting the “primary motivation” theory).

“Knowingly” and “willfully” mean that a party has acted with a purpose to commit a wrongful act. *Berkeley Heartlab, Inc.*, 225 F. Supp. 3d at 510 (citing *U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000)). The United States does not need to prove that the defendant knew the arrangement for referrals violated the statute, but only required knowledge that the conduct was unlawful. *See U.S. v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (“Indeed, the giving or taking of kickbacks for medical referrals is hardly the sort of activity that a person might expect to be legal.”). The Government need not prove that a defendant had a specific intent to violate the AKS. *See* 42 U.S.C. § 1320a-7b(h).

A. The Analyzer Schemes

McHugh arranged for the provision of desktop analyzers to doctors to perform qualitative testing to induce them to refer samples for quantitative testing at PCLS. A desktop analyzer is a piece of laboratory equipment that a physician can use in an “in-office” lab for purposes of performing qualitative UDTs (JT 23:14-22; MR 32:8-11). In order to operate an analyzer lab in-office, a doctor had to, among other things, obtain the equipment and CLIA licensure, and serve as or employ a certified lab director (MK 104:8-12). The tangible benefit of this arrangement to the provider was two-fold: (1) the provider received valuable goods and services under the guise of a sham rental or lease agreement; and (2) once up and running, the analyzer lab served as an additional revenue stream for the provider, which was particularly enticing after the Medicare program cut reimbursement for physician point-of-care testing (JN 25:2-8; MK 108:4-23; Ex. 6).

Specifically, in 2011 the Center for Medicare and Medicaid Services (“CMS”) introduced a new Healthcare Common Procedure Coding System test code, G0434, for qualitative point-of-care drug testing for multiple drug classes “to limit billing for such testing to one time per patient encounter.” (Ex. 7, p.2). This drove down the reimbursement providers previously received from such testing, which providers had typically been doing in-office by dipstick/point-of-care urine cup (MS 35:8-38:6; JN 16:4-9). At this time, conversations at PCLS about desktop analyzers became more frequent because providers—with the proper equipment—could get back to similar reimbursement rates for point-of-care testing (JG 90:7-25).

Kumar and McHugh discussed this internally (PM 170:21-171:23, Ex. 6). Kumar noted the one benefit to PCLS of providing doctors with analyzers would be that, as to the practices receiving the analyzers, “our lives are intertwined” (Ex. 6). Kumar eventually pitched this revenue opportunity to providers in connection with the offer to provide lab set-up and related services (Ex.

9). Ultimately, while PCLS discussed the provision of analyzers or related services to physicians internally, including the use of third-parties to assist physicians, PCLS witnesses testified that the company discontinued its pursuit of that avenue of business (JT 23:23-25:16; AC 62:8-21; MS 38:20-21; MR 31:17-18, 33:24-34:7, 55:5-17, 57:9-58:1). However, unbeknownst to others at PCLS, McHugh and Kumar arranged and paid, or offered to pay, for the provision of desktop urine drug test analyzer equipment and related lab set-up services for Drs. John Nickels and John Johnson—both UOFL customers—to induce referrals from their practices to PCLS.

1. *The analyzer related kickbacks to Dr. John Nickels*

Nickels was a pain management provider and the owner-operator of the Cleveland Back and Pain Management Center (JN 10:20-11:17).⁴ PCLS was courting Nickels' business in the spring of 2012 (PM 182:17-184:16, Ex. 10). To induce referrals from Nickels, Kumar and McHugh provided multiple forms of remuneration related to Nickels' analyzer lab.

The first was the analyzer itself. Kumar facilitated Nickels' lease of a Mindray BS200 Immunoassay desktop analyzer from Alternative Biomedical Solutions ("ABS") (Ex. 11; JN 30:20-25),⁵ and engaged the services of Clinical Lab Consulting LLC ("CLC") to provide consulting services on his behalf (MK 121:23-122:4; JN 58:22-60:3). Nickels agreed to run his patient samples through the analyzer for qualitative testing and then send the same samples to PCLS for confirmation testing (JN 28:8-14, 55:7-18). In return, McHugh and Kumar reimbursed Nickels directly, and paid third parties for expenses related to his analyzer lab. For example, under the lease agreement, ABS charged a fee for reagents for each test run—the fee was between \$17

⁴ In 2015, Nickels pleaded guilty to one count of health care fraud and one count conspiracy to commit money laundering. *See* N.D. Ohio Case No. 1:14-cr-447.

⁵ Nickels initially thought Kumar worked for ABS, but later learned he was an agent for PCLS (JN 18:7-19; 19:22-24; 21:10-22:22).

and \$22 and fluctuated based on the amount of testing performed, as the price per test decreased as the volume of testing increased. (JN 19:5-24; 21:1-9). Nickels sought reimbursement from Kumar and McHugh for these fees (*Id.*).

Next, Nickels routinely invoiced Kumar for amounts “owed to him” (Ex. 12, 13, 14, 15). For instance, in November 2012, Nickels wrote to Kumar that he had approximately \$8,400 in expenses that needed to be reimbursed per his “agreement with Phil.”⁶ (Ex. 12, p.1). On multiple occasions, Nickels sent itemized lists of costs to Kumar for payment that included many items for which there can be no legitimate explanation as to why a doctor would request payment from an outside toxicology lab to which he referred samples, such as (1) the salaries of two of Nickels’ employees, (2) office items such as “supplies,” urine cups, a cart, printer toner, and a refrigerator, and (3) reimbursement for ABS’ per-test fees. (Ex. 14, p.3; Ex. 15).

Expenses related to Nickels were paid, and these payments constitute remuneration under the AKS. Nickels testified that every other month or so, Kumar would deliver a check to him (JN 36:1-17). Documents produced show that from March 21, 2012 through January 8, 2013, Kumar’s company, MK Land Holdings, issued checks to Nickels totaling at least \$5,500, and to CLC, on behalf of Nickels’ practice, in the amount of \$9,483.64.⁷ (Ex. 47, 48). Notably, at the time, Nickels understood these checks to be coming from PCLS. (JN 39:6-21). Moreover, there were likely other payments for which documentary evidence has not been produced, as in an email dated November

⁶ Nickels later testified that the email was “probably Phil McHugh,” but that he “truly” couldn’t remember what the agreement was about (JN 43:22-44:1-5; 44:9-15).

⁷ Nickels testified that he did not know why MK Land Holdings wrote checks to CLC referencing Cleveland Back and Pain (JN 61:9-62:19). Kumar also testified that he did not recall if or why he or MK Land Holdings made these payments (MK 154:1-23, 155:13-16, 161:8-20, 157:2-9; 158:25-160:11, 160:23-161:7).

26, 2012, Nickels references receipt of a payment from Kumar in the amount of \$9,000 on September 11, 2012 (JN 46:6-47:5; Ex. 13, p.1).

While McHugh now denies his involvement in this scheme and knowledge of payments for Nickels' desktop analyzer lab (PM 177:23-178:18), Nickels' testimony and the contemporaneous documents from the time of the scheme reflect that McHugh was intimately involved. Nickels stated that he met with McHugh during the lab set-up process, and McHugh was "talking about the company [PCLS] that was going to be doing the confirmation testing" (JN 55:7-19). Further, on April 30, 2012, Kumar sent an email to McHugh, subject "J Nickels":

Hi Phil,

The Expense till date has been approx. \$4000. The break up is \$2726 for COLA, \$276 for API, \$750 for CLC first installment and \$120 for advertisement. The next envisaged expenditure is another \$2000 for CLC, approx. \$1000 for consumables and \$1500 for the first month for the Lab Director.

Could you send me a check for \$9000.

(PM 178:20-181:1, Ex. 16). Within a day or so of this email, McHugh wired \$10,000 into Kumar's account (PM 181:4-24; Ex. 46). Kumar also kept McHugh advised of meetings with Nickels, writing in a November 2012 email that his ticket to travel to Cleveland was "a bit expensive," but that "considering the potential gain in the number of samples" he was going to meet Nickels for dinner (Ex. 17). Kumar and McHugh stopped paying Nickels' expenses when Nickels replaced the ABS analyzer with his "own" high complexity analyzer, and no longer needed to send urine samples to PCLS for confirmation testing (JN 26:2-18).

McHugh and Kumar paid expenses to or on behalf of Dr. Nickels, at least in part, to induce the referral of samples to PCLS. This is supported by internal communications, for instance, McHugh and Kumar discussed acquiring Nickels' business: in an April 8, 2012 email Kumar wrote

that “Phil is attempting to get back Dr. John Nickels from Cleveland. It is expected that he will be back with us by July/August” and then later on in the email chain, writing:

His lab is likely to be up and running by Mid-June. It is expected that he would switch to us at that stage or soon after.

What do you opine Phil?

(Ex. 10). Notably, Kumar testified that this email was about Nickels and that it meant “[t]hat he will probably switch wherever he is at—I think he was with United Oral Fluid and that he would switch to doing—to go to PCLS for his confirmations.” (MK 148:8-14).⁸ Kumar’s assumption was correct: the claims data shows that Nickels began referring samples to PCLS on June 14, 2012. (Ex 18, p.16).

Moreover, even after acquiring Nickels’ business, McHugh and Kumar further discussed the volume of Nickels’ referrals—for example, Kumar told McHugh that he would “plan to see [Nickels] . . . and see how we can get all his samples instead of the measly number he is sending right now” (Ex. 17, p.2). To that end, Kumar also pushed Nickels to do more testing (JN 24:11-20; JN 68:15-69:9). Kumar also reviewed the practice’s billing and collections, according to Nickels, “in hopes that we would start sending more tests to them [PCLS].” (JN 68:10-14; Ex. 17). As Nickels clearly testified: “Q: Did Mr. Kumar ever indicate to you that he would like for you to send more tests to PCLS? A: **Yes, absolutely.**” (JN 69:6-9) (emphasis added).

Thus, the evidence shows that McHugh and Kumar paid Nickels remuneration related to his analyzer lab, at least in part, in order to induce referrals to PCLS. Conversely, the testimony of McHugh and Kumar does nothing to create a genuine issue of material fact. McHugh denied participation in the Nickels analyzer lab and failed to recall his involvement (PM 176:3-177:22).

⁸ McHugh reviewed that email during his deposition and testified he did not know what it was about (PM 183:8-184:16).

McHugh did not remember reimbursing Kumar for Nickels' requested expenses, and both he and Kumar testified they could not recall the reason for that wire transfer (PM 178:23-179:18, 182:2-16; MK 155:22-157:17, 162:24-163:11). Kumar and McHugh disclaimed knowledge of an agreement between McHugh and Nickels (MK 151:6-12; PM 184:19-186:6). Despite their frequent communication, and the exchange of money, Kumar testified that "he may have had some conversations with [Nickels], but I do not recall anything about him" and did not recall to what extent he was involved in the analyzer lab set-up (MK 145:8-12; MK 149:2-6).⁹ But a fact is not in dispute "simply because a witness at her deposition cannot remember whether alleged events happened," *U.S. v. Compassionate Home Care Svcs., Inc.*, 2017 WL 1030706 at *3 (E.D.N.C. March 15, 2017), and their testimony amounts to nothing more than conclusory statements and self-serving denials, unsupported by corroborating evidence. In fact, much of their testimony is undermined by other credible evidence—and as a result, it is insufficient to defeat summary judgment.

2. *The analyzer-related kickbacks to Dr. Johnson*

Johnson was an anesthesiology and pain management provider at Lighthouse Medical, a practice he owned with multiple locations in and around Johnstown, Pennsylvania. (JJ 11:1-12:11; 25:16-26:4). Johnson was a customer of UOFL (JJ 16:19-23). In the spring of 2012, Johnson contacted PCLS sales rep Elan Colen to learn more about PCLS' offerings—and "arrangements" they could make for him to obtain an analyzer (Ex. 19, 20). Colen introduced Johnson to Kumar (Ex. 21).

⁹ Nickels, however, testified that when the analyzer was up and running, initially, Kumar visited his practice about once a month (JN 25:22-25).

Johnson testified that McHugh and Kumar were aware that he was receiving kickbacks from UOFL and pitched PCLS by stating a relationship with it would be “more compliant,” “less likely to be discoverable,” and “not so obvious” as his kickback arrangement with UOFL (JJ 27:1-28:20).¹⁰ Johnson described McHugh and Kumar’s proposal as follows:

The arrangement was that there wouldn’t be money changing hands; okay? But what it was was [sic] PCLS had set me up with an analyzer where I could do the qualitative testing and submit the billing for that, and the reimbursement was significantly more than the point-of-care cups. And so that they would bill for that, but in return I would send to them for quantitative testing all the samples that I ran on the analyzer. That was the arrangement.

(JJ 28:25-29:9). He further described the arrangement as “*quid pro quo*” and illegal (JJ 46:16-25).

Johnson regularly communicated with McHugh and Kumar regarding the analyzer lab (Ex. 33; JJ 32:13-21). And when Johnson was “dragging his feet,” Kumar and McHugh met with him to discuss the particulars of the proposed arrangement—they offered to set up the lab, provide the machine and lab director, and “make sure the system ran smoothly” (JJ 34:14-36:8). In return, Johnson was to pay \$10,000 as a down payment towards the machine, and “[t]here were a certain number of samples that they wanted per month that it was told to me that they had to cover their costs . . . it was 200 samples, around – maybe 250” (JJ 34:9-21; 36:2-8; 46:2-5; 128:11-129:3).

In addition to Johnson’s testimony, contemporaneous emails demonstrate McHugh’s involvement in providing the analyzer lab to Johnson. In April of 2012, McHugh emailed Kumar regarding “Dr. Johnson Checklist,” and attached a document titled “Dr. Johnson’s Lab List,” which contained 14 bullet point items related to setting up an in-house analyzer lab (PM 191:3-25, Ex.

¹⁰ In 2017, Johnson pleaded guilty to one count of conspiracy (18 U.S.C. § 371) for his role in accepting \$2.3 million in kickbacks in connection with the above-described UOFL scheme, and to one count willful failure to remit employment taxes (26 U.S.C. § 7202) (JJ 16:24-17:23; 24:19-25:2). *See U.S. v. Johnson*, 3:17-cr-21 (W.D. Pa.).

22). Further, Kumar also noted in an April 26, 2012 email to Johnson regarding the plan that “Phil has already made contact with the supplier of the Olympus Au400 [the analyzer] and would have attractive financing options available.” (Ex. 23, p.1, 8). Thereafter, on May 14, 2012, after more back-and-forth with McHugh and Kumar, Johnson emailed McHugh that he was “[r]eady to rock and roll” on the analyzer lab—to which McHugh responded, “Manoj and I will take care of the rolling... you handle the rockin! ☺ ... Will also tell Dr. Colon to start working on ... getting up to your clinics and switching over from Millennium”¹¹ (Ex. 24; PM 192:18-194:8). This email clearly indicates that (1) McHugh offered remuneration to Johnson in the form of setting up his analyzer lab, and (2) McHugh expected referrals would be switched over to PCLS in return.

Johnson was given a contract to finance the purchase of a refurbished analyzer from Kumar’s company, MHS—as discussed between McHugh and Johnson—which he signed in July 2012 (Ex. 25, 26). Kumar’s company MHS then made a \$17,000 down payment to Diamond Diagnostics for an Olympus AU 400 desktop analyzer August 8, 2012 (Ex. 28, 29). McHugh requested the quote for this analyzer, and specified it was not a PCLS purchase (PM 207:6-21; Ex. 28). According to an email sent by Kumar, Johnson did not make his \$10,000 payment until November, and he lost the original machine—but Kumar procured another. (Ex. 29).

Johnson began referring samples to PCLS prior to the lab set-up because “they wanted a good-faith gesture that I was going to send them samples that they weren’t going to invest all this time and money in me and then me not send them samples later on.” (JJ 33:3-20). PCLS tracked the number of samples Johnson sent in, and at times, pressured and complained about the numbers to Johnson. (JJ 37:23-38:6; 39:8-40:11, 41:22-43:17; Ex. 30, 31). Johnson ultimately backed out

¹¹ Millennium was another toxicology laboratory. *See, e.g.*, <https://www.justice.gov/usao-ma/pr/millennium-laboratories-pay-256-million-resolve-false-billing-and-kickback-claims>.

of the deal with McHugh before receiving the analyzer, and eventually stopped sending samples to PCLS because he was reluctant to damage his relationship with UOFL and Hughes (JJ 30:12-31:19; 32:2-12; 126:9-10).¹²

Notably, even though Johnson did not receive the analyzer, McHugh is still liable under the AKS because he offered, and he and Kumar provided, things of value to Johnson, including, among other things, assistance in obtaining CLIA licensure, procuring the analyzer, software integration, and the purchase of other necessary equipment (JJ 59:11-61:21). All items of value offered were detailed in an email from McHugh (Ex. 23, p.8) and discussed in great detail by Johnson during his deposition (JJ 50-67). Whether paid or simply offered, this constitutes remuneration under the AKS, as the statutory language plainly makes it a violation to “knowingly and willfully **offer or pay** any remuneration . . . to induce the referral of business reimbursable under a federal health care program.” 42 U.S.C. § 1320a-7b(b)(2) (emphasis added).

Against the documentary evidence and Johnson’s unequivocal testimony, McHugh testified that outside of giving Johnson “information,” he had no involvement in the analyzer lab (PM 189:5-190:10), and that he had no knowledge of MHS’ down payment (190:12-25). Kumar testified that his role was limited to the introduction of Johnson to CLC, which would provide him with services related to the analyzer lab and that his only intention was to present Johnson with options from various vendors (MK 121:8-122:14). These self-serving statements—supported by no corroborating evidence and in direct contradiction to contemporaneous emails and documents—are insufficient to create a fact issue.

¹² During McHugh’s examination of Johnson, he added that he backed out because he did not believe he could afford the analyzer that PCLS was procuring for him (JJ 123:11-124:25).

B. The Loan Schemes

McHugh paid kickbacks disguised as loans to induce the referrals of UOFL customer Dr. Orlando Florete and his practice, the Institute of Pain Management (“IPM”),¹³ and later, to obtain the business of Kumar’s acquaintance, Dr. Sanker Jayachandran. Both Florete and Jayachandran were in financial trouble at the time they received the loans (OF 27:19-28:14; Ex. 32, SJ 23:20-24, 25:19-28:20), and McHugh—despite knowing Florete needed the money to pay off the IRS and other creditors—did limited due diligence into Florete’s ability to pay back the loan (PM 64:4-65:14), and neither McHugh or Kumar did any due diligence at all as to Jayachandran (PM 107:24-108:18), despite Kumar knowing Jaychandran was “already in great debt” when he came to Kumar for the loan. (MK 166:4-167:4).

1. *McHugh’s two million dollars in loans to Dr. Florete*

PCLS began targeting Florete in or around the spring of 2013. PCLS sales rep. Chris Kemp described Florete and IPM as a “big account” based on the volume of pain medications prescribed and stated that PCLS wanted all of his business (CK 13:2-15:11, 24:20-24, 29:15-31:12). Kemp spent several months trying to earn Florete’s business (CK 15:12-16:3), and Florete had not used PCLS prior to Kemp securing his account (CK 18:25-19:7, 57:15-58:19). IPM eventually became Kemp’s largest account based on volume of referrals (CK 33:2-8).

In July 2013, Kemp sent an email up his chain of command indicating that Florete was ready to “begin a partnership with us” (PM 71:1-21, Ex. 34). Kemp arranged for Florete to visit PCLS’ lab in August, to meet with, among others, McHugh. McHugh testified that during the meeting, he mentioned that was in the business of making loans, and Florete asked for a loan (PM

¹³ Other IPM providers who referred to PCLS during the alleged kickback scheme are identified at Ex. 18, p. 11; *see also* Ex. 36, 63, 64.

57:2-6). At the time, Florete was in debt to Hughes and UOFL, PCLS' competitor, as the result of a purchase agreement that Florete backed out of (OF 22:4-17, 41:19-43:5; PM 57:7-15). Florete did not seek a loan from a bank or any other source before soliciting McHugh (OF 56:9-18).

McHugh's company, Silent Storm,¹⁴ subsequently loaned IPM and Florete's holding company, Aries Medical Corporation ("Aries"), \$1.7 million on October 18, 2013 (Ex. 35; PM 55:4-57:2, 61:1-9; 67:23-68:22, 92:17-24, 94:4-9). In March 2014, despite Florete's failure to make timely and complete repayments,¹⁵ McHugh entered into a loan modification, lending an additional \$300,000 in funding to IPM because either Florete's lawyer or office manager asked for it (PM 67:1-13, 68:23-70:9, Ex. 37). Florete testified that he didn't know why the loan was modified (OF 55:2-8). Florete currently owes over \$2.5 million on the loan, and within the last several months has been discussing ways to mitigate his debt to Silent Storm with McHugh (OF 89:9-91:8).¹⁶

It is axiomatic that a loan is cash or in kind, and thus, \$2 million in loans constitutes remuneration under the AKS. While McHugh contends that the loans were arms-length transactions and that he intended for the loans to be repaid, even if true, those facts are irrelevant—the loans still constitute unlawful remuneration under the AKS because at least one purpose of the loan was to induce referrals. *See U.S. v. Kruse*, 101 F. Supp. 2d 410, 412 (E.D. Va. 2000) ("Because the loans were things of value provided for the purpose of rewarding favorable treatment, the Court FINDS that the principals of the loans constitute 'kickbacks' for the purposes of the Anti-Kickback statute."); *see also U.S. v. Kemp*, 500 F.3d 257, 285 (3d Cir. 2007) (holding

¹⁴ McHugh is an owner and the manager of Silent Storm, which he described as a holding company, and testified that he "believed" he made decisions on behalf of the company (PM 12:23-17:12).

¹⁵ Bank records reflect that Florete made one payment of \$9,916.67 before the loan modification. (Ex. 39).

¹⁶ McHugh denies this (PM 99:19-100:2).

loan may support bribery prosecution and noting the conclusion a loan may constitute the *quid* in a bribery “also takes account of the commonsense notion that a loan may be of immense value to the recipient: for instance, here, Kemp's mortgage loan allowed him to purchase a house.”) (discussing authorities).

The undisputed evidence on this issue is that: (1) McHugh was aware Florete was a pain management doctor, the type that would refer patients to PCLS (PM 79:24-80:4); (2) Florete was the sole owner of IPM (OF 8:17-20), and “the decision maker . . . everything started and stopped with him”¹⁷ (CK 19:15-20; 60:13-61:7); (3) Florete, when he met McHugh at the time, knew that McHugh was “one of the key people at PLCS” and “one of the owners” (OF 34:2-17); (4) McHugh knew that Florete wanted the original \$1.7 million in loan money to buy himself out from a failed purchase agreement with UOFL and Bill Hughes (PCLS’ competitor) (PM 57:7-15); and (5) as Florete testified, “I talk about it and he [McHugh] offered that he can provide the funding to pay off Mr. William Hughes” (OF 22:15-17). And when asked by another attorney why McHugh was making the loan, McHugh’s transactional attorney handling the deal replied by email in September 2013 that:

It is my understanding that Phil is trying to get Dr. Florete to come up and work for PCLS. Apparently Dr. Florete made some business deal with another guy that isn’t working out, so Phil is trying to free Dr. Florete from that situation.

(Ex. 43).

McHugh testified that he made the loan because he was in the business of lending money (PM 55:4-57:2, 61:1-9; 92:17-24; 94:4-9) and his attorney told him it was OK for him to do so

¹⁷ Florete testified he had “hardly any” role in selecting the lab and that sometimes he wasn’t asked (OF 60:6-17) however, this self-serving testimony does not create a genuine fact issue in light of the other credible evidence presented. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(1) (AKS provides for criminal penalties to those who solicit or accept bribes or kickbacks in exchange for referrals).

(PM 62:20-22; 81:4-85:13). He stated that he did not consider whether making the loan would improve PCLS' business relationship with Florete (PM 80:5-14). Testimony from an owner of a company that he did not ***consider at all*** the impact that providing \$1.7 million to a potential client—so that client could buy himself out a relationship with a competitor—would have on the business relationship with that client is the type of self-serving testimony a court should find incredible. *See Gray v. Spillman*, 993 F.2d 1537, 1993 WL 165039 at *3 (4th Cir. 1993) (unpublished).

Moreover, claims data and testimony reveal the loan negotiations had an impact on the volume of referrals from Florete's practice: (1) after months of sales calls from Kemp, Florete finally "signed on" with PCLS in September of 2013 (CK 15:12-16:3, 20:3-16; 69:9-19; 73:8-21)—consistent with the time frame during which McHugh and Florete were negotiating (Ex. 44), and ultimately entered into the \$1.7 million loan, (2) specifically, Florete and four other IPM providers signed the PCLS Provider Acknowledgement Form ("PAF") establishing their standing orders with the lab on September 17, 2013, one month before Florete and McHugh finalized the loan (Ex. 36)¹⁸; and (3) Kemp recalled that IPM referrals then went from a "standstill to a sprint" (CK 32:6-13), consistent with the fact that Medicare claims data reflects a smattering of claims for reimbursement to PCLS for IPM samples in the third quarter of 2013 and a spike in the fourth quarter of that year (Ex. 18, p. 40).¹⁹

¹⁸ Kemp described the PAF as an on-boarding document that was signed by a new customer at the inception of its relationship with PCLS (CK 35:9-36:20).

¹⁹ This is consistent with Johnson's testimony that McHugh required a provider to make a "good faith" showing of referrals prior to receiving his kickback.

2. *McHugh and Kumar's \$50,000 loan to Dr. Jayachandran*

After the Florete loan, McHugh, along with Kumar this time, made another sham loan to a physician to induce referrals. Dr. Jayachandran is a psychiatrist in Indiana and is an owner of Confidential Care (SJ 10:5-19). Jayachandran began using PCLS, among other labs, for UDT sometime in 2011 or 2012 and claims that he was using PCLS to some extent through 2014 (SJ 16:1-15; 18:6-17). Kumar indicated, however, that Jayachandran began referring to PCLS shortly before the loan was made (MK 171:2-8).

In the summer of 2014, Kumar negotiated a \$50,000 loan on behalf of McHugh's newly-formed entity, M Holdings, LLC, to Jayachandran (PM 27:9-23; MK 165:14-19; Ex. 45). At the time, Jayachandran understood Kumar to be a sales rep for PCLS (SJ 16:21-17:4). In July 2014, Jayachandran appears to have "renewed" his PAF (SJ 21:21-23:17; Ex. 49). Approximately one month later, without having met or spoken with Jayachandran, McHugh wired \$50,000 to the account of Jayachandran's wife (SJ 34:17-36:12; Ex. 50), \$25,000 of which Kumar contributed (PM 104:9-105:20). Jayachandran testified that he didn't remember getting this particular loan, because he had financial difficulties as a result of the opioid crisis and sought and obtained multiple loans during that timeframe (SJ 23:20-24, 25:19-28:20).

McHugh believed Jayachandran was a PCLS customer when he made the loan (PM 107:4-8), but, as with Florete's loan, he testified that he did not consider whether the loan to Jayachandran would impact the volume of samples he referred to PCLS (PM 107:9-13), however, he: (1) does not recall if he did any due diligence as to Jayachandran's financial status or ability to meet his repayment obligations (PM 107:24-108:18); (2) made the loan without ever meeting or speaking to Jayachandran (PM 102:9-13); (3) did not disclose the Jayachandran loan to anyone at PCLS (with the exception of Kumar) before he made it (PM 106:2-12), and (4) was surprised when PCLS

found out about the loan, writing to Kumar “[t]hey [PCLS] are investigating me on this now. How the heck did they get this doc?” (PM 108:22-109:8, Ex. 51).²⁰ Kumar testified he also did no due diligence as Jayachandran’s ability to meet his repayment obligations (MK 167:1-14).

The only possible inference from the evidence is that at least one purpose of the loan to Jayachandran—whom McHugh had never met and never requested any diligence into his ability to repay the loan—was to influence the volume of Jayachandran’s referrals to PCLS, and induce more.

3. *The defenses to the loan schemes McHugh has raised are unavailing.*

McHugh raises two defenses to the loan schemes properly addressed on this Motion. First, McHugh contends that Medicare was reimbursed for claims it paid related to the referrals induced by the Florete and Jayachandran loans. But there is simply no evidence this purported “repayment” ever occurred. First, like McHugh himself, no PCLS employee deposed in this case could testify to any personal involvement in making the repayment or any personal knowledge of any specifics regarding the repayment, such as the amount of the repayment, when it occurred, how it occurred, or most importantly, if it actually occurred. (JW 62:12-63:3; MS 74:14-75:2; AC 50:25-54:25; PM 114:18-117:18). Second, the Government extensively investigated this issue, and its un rebutted 30(b)(6) testimony is that no repayment occurred. (JS 13:12-17:14; 25:22-26:13).

Second, McHugh asserts that he relied on the advice of counsel prior to making the Florete loan—testifying that his attorney Anna Winger provided an opinion to him that the Florete loan was AKS compliant *before* he made it (PM 80:23-85:10)—and that he subsequently relied on the

²⁰ When PCLS discovered the Florete and Jayachandran loans, it took certain actions, including discontinuing its relationship with those providers (PM 112:18-113:12). PCLS also directed McHugh to get his money back from Jayachandran (PM 113:7-10; MK 169:18-25). Jayachandran refunded the principal balance on December 20, 2014 (SJ 36:20-37:8, Ex. 52). He got the funds for repayment from a Dr. Gupta, who he was introduced to by Kumar (SJ 31:24-33:25).

advice given then in making the Jayachandran loan. (PM 102:14-25). Winger’s testimony, and the document evidence such as billing records and emails, all indicate this statement by McHugh is patently untrue. To prevail on an advice of counsel defense, McHugh must establish that he: (1) sought the advice in good faith; (2) provided full and accurate information to his attorney(s); (3) reasonably relied on the advice; and (4) faithfully followed that advice. *United States v. Butler*, 211 F.3d 826, 833 (4th Cir. 2000), *cert. denied*, 531 U.S. 1149 (2001).

First, McHugh designates two attorneys as persons with relevant knowledge in this case—Winger and Patricia Markus. Winger, who is primarily an estate planning attorney, testified that she has no AKS experience or specialization, merely served in a transactional role regarding the Florete loans when they were made, and unequivocally stated that she did not give McHugh advice as to whether or not the loan complied with the AKS, and that she did not procure such advice from another legal professional or other source (AW 7:21-25, 8:3-7, 9:9-10:2, 19:21-20:8, 26:12-23, 28:2-29:8). And without giving such advice, the mere fact that Winger or other attorneys were involved in the loans does not implicate the advice of counsel defense. *See U.S. v. Powell*, 680 F.3d 350, 356–57 (4th Cir. 2012), *cert. denied*, 568 U.S. 922 (2012) (advice-of-counsel instruction would not be appropriate where “no evidence indicated that [defendant] disclosed facts, pertinent or otherwise, to [counsel]” and such counsel “acted only as a scrivener...”); *U.S. v. Berkeley HeartLab, Inc.*, 2017 WL 4803911, at *9 (D.S.C. Oct. 23, 2017) (“Defendants cannot use the advice of Mr. Sellers to shield them from liability for violating the AKS with their Commission Payment arrangement because Sellers did not advise or offer any legal advice to the BlueWave Defendants about the AKS.”).

Next, while Markus did give an opinion on AKS compliance and the Florete loan, even assuming *arguendo* her opinion was based on full and accurate information (it was not), it was

provided in an October 9, 2014 email—long after both the Florete loans (October 2013 and March 2014) and Jayachandran loans (August 2014) were made (AW 50:7-24; Ex. 53). It is axiomatic that McHugh, in October 2013 when he first made the Florete loan, could not have relied on a legal opinion not given until a year later in October 2014. *See Vernon*, 723 F.3d at 1270 (evidence that kickbacks began well before any consultation with a lawyer belied defendant’s contention that he relied on good faith advice of counsel). And Winger’s testimony, along with both attorneys’ billing records, confirm no AKS related work was performed for McHugh until September/October 2014. (Ex. 54, AW 24:5-25:2, 26:12-27:3, 41:18-42:8, 44:15-45:2, 53:3-12).

C. The Kumar Compensation Scheme

McHugh violated the AKS by arranging for Manoj Kumar to be paid kickbacks under the guise of employment agreements with PCLS to induce referrals from two Indiana pain management practices (Drs. Shah and Masimore) that Kumar managed. These physicians, who had previously never sent a sample to PCLS, ultimately referred over \$1,985,351 in claims paid. (Hines, p.13, Blevins, Ex.1, p.1).

1. *It is undisputed that Kumar was paid volume-based commissions from the referral of UDTs to PCLS from physician practices he concurrently managed.*

There is no dispute as to many of the foundational facts related to Kumar’s employment agreements with PCLS and prior/concurrent management of physician practices. Kumar was first an independent contractor for PCLS (Ex. 55; PM 122:12-14), and later, a W-2 employee with the title of Vice President of New Business Development (Ex. 56; PM 135:10-14). It is undisputed that Kumar concurrently provided services to the physician practices for Drs. Masimore and Shah and was paid by those doctors to do so (MK 16:13-19; YS 24:4-25:4, 38:1-21, 47:6-48:2, YS 49:12-54:20, 85:6-24 Ex. 38, GM 13:12-17:13, Ex. 40). It also is undisputed that Drs. Masimore and Shah referred UDTs to PCLS from their practices managed by Kumar (Ex. 18, p.12-14). And

it is undisputed that Kumar—both as an independent contractor and then as a W-2 employee of PCLS—received compensation (*i.e.*, remuneration) in the form of volume-based commissions for the samples that Drs. Shah and Masimore referred throughout his employment with PCLS (MK 59:2-10, 60:20-61:23, 66:20-68:3).

2. *The employment agreements with Kumar were entered into at McHugh's direction and for the purpose of inducing samples from Drs. Shah and Masimore.*

The evidence further establishes that McHugh negotiated and arranged for these employment agreements with Kumar to induce the referral of samples to PLCS. Indeed, McHugh long saw Kumar as someone who could direct samples to PCLS—for example, in 2009, when Kumar managed a large physician practice (Dr. Kamal Tiwari's practice at Pain Management of Southern Indiana) (MK 10:25-11:24), McHugh wrote in an internal e-mail regarding Kumar:

A potential large customer, Manoj . . . will be paying us a visit Thursday . . . If he likes what he sees . . . we will pick up his samples . . . If not...no samples.

(Ex. 41).PLCS was unsuccessful in picking up samples from Dr. Tiwari's practice at the time (Ex. 42, p.1), and that practice fell apart due to Tiwari's indictment and conviction on health care fraud and drug distribution charges. (Docs 1, 107 in S.D. Ind. Case No. 1:10-cr-00103). However, Drs. Masimore and Shah, two of the physicians from Tiwari's practice, each set out on his own, independently hiring Kumar to help start and manage their practices (Masimore's solo practice began in November 2010, GM 8:20-9:4, 19-24; and Shah started solo practice in late 2010, YS 12:23-16:11, 17:16-25).

Around the same time period, Kumar began negotiating an employment arrangement with PCLS (Ex. 57). When exactly Kumar became an independent contractor for PCLS is somewhat unclear—the independent contractor agreement produced in this case is dated November 1, 2010, but was only signed by Kumar. However, email correspondence between McHugh and Kumar in

December of 2010 reveals that Kumar's role with PCLS was still unsettled at that time, though according to McHugh, by then Kumar was "responsible for bringing on physicians and could bring on more" (*Id.*).

What McHugh and Kumar's email correspondence does make clear is that Kumar represented to McHugh he could control where Shah and Masimore sent their business and that "signing on" the physicians to PCLS was a part of McHugh and Kumar's negotiations as to Kumar's role at PCLS. (*Id.*; Kumar writing to McHugh that "While I myself am not seeking new physicians, there are those that I have already signed on, those that seek my advise/suggestions [sic] . . . and those that I personally know and could possibly influence in some way . . . I am not focusing on sales myself except in cases such as Masimore (who I have signed on . . .), Shah (who will go the way I advise . . .)."

Testimony from Masimore and Shah confirms Kumar's influence on where the doctors sent their samples. First, Dr. Masimore invoked his Fifth Amendment privilege against self-incrimination when questioned about why he sent samples to PCLS and whether Kumar directed or influenced that decision (GM 17:21-19:2; 20:22-24). The Court should draw an adverse inference against McHugh and Kumar from this invocation, as the Fifth Amendment "does not preclude in a civil case the admissibility of the assertion of the Fifth Amendment privilege or an adverse inference." *Cargill, Inc. v. WDS, Inc.*, 2018 WL 1525352, at *11 (W.D.N.C. Mar. 28, 2018) (citing *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976)). In *Cargill*, Judge Whitney concluded that the allowance and admission of a negative inference against the defendants based on a non-party's invocation of the Fifth Amendment was proper when, *inter alia*, the non-party witnesses maintained close business relationships with the defendants, received items of economic value from the defendants, were key figures in the case, and the defendants benefited from the

invocation of the “Fifth Amendment privilege as it prevent[ed] the uncovering of additional facts and evidence.” *Id.* at *12.

So too should an adverse inference be drawn against McHugh from Masimore’s invocation, as Masimore is a key figure in the case who had a formal business relationship with Kumar and PCLS, still owes Kumar money for his services as practice manager (YS 47:24-48:2), and there is no indication that Masimore’s invocation of the privilege is anything but trustworthy. *See Coquina Investments v. TD Bank, N.A.*, 760 F.3d 1300, 1312 (11th Cir. 2014) (finding non-party witness invocation in civil case trustworthy and drawing adverse inference against defendant); *Cerro Gordo Charity v. Fireman’s Fund Am. Life Ins. Co.*, 819 F.2d 1471, 1482 (8th Cir. 1987) (“Richards is also a key figure in this case. . . . Hearing Richards invoke the privilege informed the jury why the parties with the burden of proof, i.e., the insurance companies, resorted to less direct and more circumstantial evidence than Richards’ own account of what had occurred.”).²¹

Conversely, Shah testified on these subjects in his deposition, and stated that Kumar recommended PCLS to him and suggested that Shah go with PCLS.²² (YS 55:17-56:10). He never considered using any other labs, never talked to anyone at PCLS before signing up with them, never saw any PCLS marketing materials, and did not talk to anyone other than Kumar about what toxicology lab to use or whether to use PCLS. (YS 56:22-58:3). Ultimately, after consulting solely with Kumar, Shah decided to use PCLS for his practice. (YS 58:4-7). Shah further stated that he did not know about Kumar’s relationship with PCLS when he started his practice and began

²¹ *See also Arminius Schleifmittel GmbH v. Design Indus., Inc.*, 2008 WL 819032, at *2, n.1 (M.D.N.C. Mar. 20, 2008) (noting invocation of Fifth Amendment privilege may be considered at summary judgment).

²² Shah testified that he was comfortable with Kumar’s recommendation as to PCLS based on using PCLS previously at Dr. Tiwari’s practice. (YS 55:17-56:10). This attempted qualification on his decision and Kumar’s recommendation is demonstrably false, as the claims data demonstrates that Shah never referred samples to PCLS while at Tiwari’s practice. (Ex. 42, p.1).

sending samples to PCLS (YS 77:7-21).²³ Thus, the only reasonable conclusion that can be drawn is that Kumar—as he represented to McHugh that he could—influenced the referrals of samples from Shah and Masimore to PCLS.

The central role that Shah and Masimore’s referrals to PCLS played in Kumar’s employment with PCLS is further bolstered by the documents themselves. First, an addendum to Kumar’s independent contractor agreement provided a “list of the clients that have been procured by MK Land Holdings” and lists both Masimore’s and Shah’s practices. (Ex. 55, p.8). As such, it cannot be reasonably contended that PCLS acquiring referrals from Masimore and Shah did not play a role in Kumar’s hiring when (a) his original agreement contains a written addendum specifically identifying those practices, and (b) McHugh and Kumar’s email correspondence specifically references this business. Likewise, when McHugh proposed to Kumar that he become a W-2 employee, McHugh wrote in email correspondence between himself and Kumar alone that one of the details of the proposed position would include that Kumar “keep all business and revenues flowing from current book of business (approx 30k per month).” (Kumar-email_00038592). Notably, McHugh testified that this sentence referenced the commissions Kumar was receiving as an independent contractor (PM 138:2-8).

Finally, the evidence demonstrates that it was McHugh who made the decision to hire Kumar originally in 2010, as well as convert Kumar from an independent contractor to employee. First, the email correspondence noted above negotiating Kumar’s employment as both an independent contractor and employee was solely between McHugh and Kumar, and includes job proposals by McHugh. (Ex. 57, 58). Further, Kumar testified that he only spoke to two people at

²³ Shah did not find out until Kumar became a PLCS employee and moved to Charlotte, and only did so because the location that he sent checks changed based on Kumar’s move. (YS 73:9-76:7).

PCLS—McHugh and Sowinski—before he initially became an independent contractor. (MK 26:16-22). As Sowinski testified that he did not have any role in bringing Kumar into PCLS as either an independent contractor or employee (outside of working to develop Kumar’s employment agreement when he transitioned from an independent contractor in 2013) (MS 51:24-58:23; 61:24-62:25), this leaves only McHugh as the person involved on PCLS’ side. Further, while McHugh mentions that others were tangentially involved in Kumar’s hiring, he describes his role in Kumar’s hiring as, among other things, “confirming with all the other individuals if they would *concur*”—*i.e.*, concur with **McHugh’s** decision to hire Kumar. (PM 124:7-15).²⁴ Finally, Phil McHugh signed Kumar’s 2013 employment agreement on behalf of PCLS. (Ex. 56, p.10).

3. ***Kumar’s compensation agreements violated the AKS.***

The independent contractor and employment agreements with Kumar that McHugh arranged, and the commissions paid to Kumar for referrals from Shah and Masimore, violated the AKS. *See MedPricer.com, Inc. v. Becton, Dixon and Co.*, 240 F. Supp. 3d 263, 271 (D. Conn. 2017) (“Courts have held that percentage-based compensation arrangements violate the AKS.”); *Zimmer Inc. v. Nu-Med Medical Inc.*, 54 F. Supp. 2d 850 (N.D. Ind. 1999) (agreement that called for independent contractor to receive a percentage of medical product sales violated the AKS).

Further, McHugh is not insulated from liability merely by virtue of the fact that Kumar was not the physician sending in the samples, as the AKS also prohibits payments to laypersons who have the ability to influence or direct referrals. *See U.S. v. Vernon*, 723 F.3d 1234, 1254 (11th Cir. 2013) (“[Defendant] argues that because [the kickback recipient] is not a physician, she could not

²⁴ McHugh testified that the “entire team” involved in Kumar’s hiring potentially included McHugh, Sowinski, Wiegall, Smith, John Grove, and Sandy Weaver. (PM 123:3-7; 124:16-22). Even if true, another PCLS employee’s mere involvement in Kumar’s hiring does not equate to that employee being a decision maker. (JG 97:14-20, PM 123:8-10, 123:11-14, JW 14:4-24).

‘refer’ patients to Medfusion within the meaning of subsection (b)(2)(A) of § 1320a–7b. This argument wholly fails because the plain language of the statute is not limited to payments to physicians who prescribe medication. Rather, it speaks broadly to ‘whoever knowingly and willfully . . . pays any remuneration’ to “*any person* to induce such person . . . to refer an individual’ to Medfusion for an item or service paid by Medicaid.” (emphasis in original).

The Seventh Circuit’s decision in *United States v. Polin*, 194 F.3d 863 (7th Cir. 1999) is particularly instructive here. There, the court affirmed AKS convictions of two defendants who were employees of a pacemaker monitoring service that made payments—based on the number of patients referred to the defendants’ employer—to an independent sales representative for the services. *Id.* at 864–65, 867. The evidence showed that the sales representative was responsible for selecting an outside monitoring service such as defendants’ company once a physician determined that such services were necessary and that although “the physician had the right to refuse any [monitoring] service he chose, . . . [the sales representative] had never been overruled by a physician during his fourteen year career.” *Id.* at 865. Ultimately, the Seventh Circuit concluded that it was a “classic case of an illegal kickback prohibited by 42 U.S.C. § 1320a–7b(b)(2)(A). In exchange for directing Medicare patients to [the defendant company], [defendants] were willing, and did, pay [the sales representatives] money.” *Id.* at 867.

The same classic kickback case is found here: McHugh arranged for Kumar to be paid money in exchange for Kumar directing the UDTs of Masimore and Shah’s Medicare patients to PCLS through his position and influence as the physicians’ practice manager. *See also U.S. v. Shoemaker*, 746 F.3d 614, 629 (5th Cir. 2014) (“Moreover, sufficient evidence established that the payments to Chandler aimed to induce him to ‘recommend’ Garner’s company. 42 U.S.C. § 1320a–7b(b)(2)(B). That is, in paying Chandler, Garner was not asking for a brochure bearing his

company's name to be distributed to TLMC staff; rather, enough evidence showed that he wanted Chandler to exploit his personal access to TLMC executives, including Shoemaker, and to ensure that TLMC favored Garner's company when it chose nursing services. This conduct is an archetypal example of the undue influence prohibited by the statute.") (emphasis added).

Importantly, no safe harbor for Kumar's employment agreements exists. For example, the personal services and management contracts safe harbor, or, "bona fide employee" exception, is established if seven standards are met. 42 C.F.R. § 1001.952(d). McHugh's arrangement of Kumar's compensation—first, for services performed as a 1099 Channel Partner through his entity, MK Land Holdings, LLC and then later as a W2 employee—are not excepted from the AKS because Kumar's compensation, under both scenarios, took into account the volume or value of referrals, payable to Medicare, generated between the parties. *Id.* at § 1001.952(d)(5) (personal services contracts must not be based on the "volume or value of any referrals"); *Nursing Home Consultants, Inc. v. Quantum Health Services, Inc.*, 926 F. Supp. 835, 844 (E.D. Ark. 1996), *aff'd*, 112 F.3d 513 (8th Cir. 1997) (agreement tied to sales volume not saved by safe harbor).

D. Further evidence of McHugh's intent and knowing and willful participation

McHugh's conduct—particularly the concealment of certain transactions from PCLS—is evidence of his knowing and willful violation of the AKS. As an initial matter, McHugh was aware of the AKS and its implications for health care providers that bill Medicare—on three separate occasions from 2009 to 2011, he signed the Certification Section of § 15 of PCLS' Medicare Enrollment Application (CMS Form-885B), indicating he understood that the laboratory was required to comply with Medicare laws, regulations and program instructions, including the AKS. (Ex. 59, 60, 61).

Kumar and McHugh took affirmative steps to conceal their activities from PCLS. For example: (1) Kumar paid Nickels by checks drawn from the MK Land Holdings account (not PCLS'); (2) Kumar sought reimbursement for Nickels' expenses from McHugh, personally (not PCLS'); (3) McHugh reimbursed Kumar from his personal account—not an account of PCLS—and if McHugh actually believed the payments to or on behalf of Nickels were “compliant,” there would be no reason to use Kumar and MK Land Holdings as the conduit for payment; (4) Kumar made the down payment on the Johnson analyzer from his company's account (not PCLS'); (5) McHugh and Kumar communicated about the Jayachandran loan using their @silentstorm email accounts—not their PCLS email accounts (Ex. 45); and (6) Kumar did not disclose his involvement with the Indiana practices before he entered into the independent contractor agreement (MK 51:17-52:3).

Additionally, multiple PCLS c-suite officers and employees were deposed and testified that they had no knowledge of the kickbacks until after they were offered or made. (MS 46:23-48:18, 49:11-17, 50:12-51:23, 59:20-25, 60:21-61:1, 75:3-5; AC 48:19-49:2, 49:22-24, 57:22-58:11, 64:1-20; JW 52:12-19, 56:10-24, 61:9-22; 68:20-23; MR 61:1-63:4). PCLS had, in fact, a compliance department and written policies or procedures related to the AKS (Ex. 62), and put on compliance and regulatory training for its sales force and Board of Directors, including trainings on the AKS (MS 20:13-25; AC 26:4-27:9). However, despite the fact that McHugh was aware of and had access to PCLS' compliance department, and could have obtained guidance and counsel as to these arrangements, he chose not to (thereby concealing his conduct from PCLS) (PM 66:11-24). *See U.S. v. Lusk*, 2017 WL 508589 (S.D. WVa. Feb. 7, 2017) (concealment of fraud probative of wrongful intent). Finally, “evidence of financial gain is particularly probative in a [health care] fraud case to establish the defendant's intent to defraud.” *U.S. v. Bajoghli*, 785 F.3d 957, 966-67

(4th Cir. 2015) (*citing U.S. v. Beverly*, 284 F. App'x 36, 40 (4th Cir. 2008); *accord U.S. v. Davis*, 490 F.3d 541, 549 (6th Cir. 2007); *see also U.S. v. Dearing*, 504 F.3d 897, 901 (9th Cir. 2007) (discussing evidence from which a fact-finder could infer willful intent to defraud); *U.S. v. Wheeler*, 889 F. Supp. 2d 64, 68 (D.D.C. 2012) (reiterating *Davis* holding in context of § 1347 health care fraud prosecution). From approximately 2011 through 2013, PCLS had close to \$100 million in profit and tax distributions among the four owners (AC 41:21-42:14), and from 2011 through 2015, McHugh received at least \$27.5 million in distributions from PCLS (PM 42:5-48:11).

III. MCHUGH'S AKS VIOLATIONS GIVE RISE TO FCA LIABILITY.

The United States is entitled to summary judgment under the FCA because, as a matter of law, McHugh's violations of the AKS also constitute violations of the FCA. Four elements must be established to prevail under the FCA: (1) Defendant submitted or caused to be submitted claims for payment to the federal Government; (2) the claims were false or fraudulent; (3) Defendant acted knowingly; and (4) the falsity or fraud was material to the Government's payment decision. 31 U.S.C. 3729(a)(1)(A); *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015) (vacated and remanded on other grounds).

As to the first element, McHugh caused claims related to the three kickback schemes to be submitted for payment to the federal government. It is undisputed that PCLS submitted claims for reimbursement²⁵ to the Medicare Program for UDTs performed on beneficiary samples. That PCLS as a company was the one to actually submit the claim does not insulate McHugh. Rather, “[t]he FCA places liability not only on persons who cause false claims to be submitted . . . but also on those who cause the claims . . . to be false in the first place.” *Mason v. Medline Indus., Inc.*, 731

²⁵ A “claim” is statutorily defined as a “request or demand, whether under a contract or otherwise, for money or property.” 31 U.S.C. 3729(b)(2).

F.Supp.2d 730, 738 (N.D. Ill. 2010) (further noting “[t]he wealth of case law supports the proposition that the FCA reaches claims that are rendered false by one party, but submitted to the government by another.”) (collecting authorities); *see also U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) (“We have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party”).

As to the second element, “[a]n AKS violation resulting in a federal health care payment automatically constitutes a false claim under FCA.” *U.S. ex rel. Hartnett v. Physicians Choice Laboratory Services, LLC*, 2020 WL 571322, at *3 (W.D.N.C. Feb. 5, 2020) (Bell, J.) (citations omitted); *see also U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498 (D.S.C. 2016) (collecting cases). Likewise, the fourth element is met as a matter of law. *See Berkeley Heartlab, Inc.*, 2017 WL 6015574 (D.S.C. Dec. 4, 2017) (“AKS violations are *per se* material.”); *U.S. ex rel. Goodman v. Arriva Medical, LLC*, 2020 WL 3840446 (M.D. Tn. July 8, 2020) (discussing materiality post-*Escobar* and in the AKS context). As to the third element, “[s]cienter under the FCA encompasses actual knowledge, deliberate indifference, and reckless disregard, but does not require proof of specific intent to defraud.” *Triple Canopy, Inc.*, 775 F.3d 628, 634 (4th Cir. 2015) (vacated and remanded on other grounds) (*citing* 31 U.S.C. § 3729(b)(1)). It is well-established that if a party has the requisite intent to induce and, as a result, violate the AKS, and causes the submission of claims for payment to Medicare, then that person also violates the FCA. *See U.S. ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259 (11th Cir. 2005).

The evidence supporting the third element is discussed in the preceding sections with regard to McHugh’s AKS violations, and demonstrates, at the very least, McHugh’s failure to make reasonable efforts to ensure that his “financial arrangements” with Nickels, Johnson, Florete,

Jayachandran and Kumar complied with the AKS *before* PCLS filed claims with Medicare for reimbursement for tests ordered by or at the direction of those individuals, demonstrates reckless disregard. *See Heckler v. Cmt. Health Svcs. of Crawford*, 467 U.S. 51, 64 (1984) (“As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements.”).

IV. DAMAGES

The False Claims Act provides for treble damages plus a per-claim penalty. *See U.S. v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (citing 31 U.S.C. § 3729(a)); *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 675 F.3d 394, 397 (4th Cir. 2012). The United States’ single damages consist of the claims submitted to Medicare that are tainted by a kickback, and thus false in their entirety. *See United States v. Rogan*, 459 F. Supp. 2d 692, 726-27 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008). (finding that United States’ damages are the value of the claims submitted tainted by kickbacks and were established by “competent evidence introduced by the Government, including the business records of CMS that reasonably fixed those amounts paid by the Government for services”). Here, the United States’ retained expert, Eric Hanes, has analyzed the claims data and calculated the single damages based on McHugh’s kickback schemes to total \$3,932,268 and involve 5940 separate claims. (Ex.18, p.7, 18).

The United States is also entitled to civil penalties in the range of \$5,500 to \$11,000, which are calculated on a per-claim basis. *See* 31 U.S.C. § 3729(a); *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 675 F.3d 394, 397 (4th Cir. 2012); *see also Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001) (“Each submission of the [CMS] – 1500 form . . . qualifies as a claim made to the United States” for purposes of calculating penalties); *Krizek*, 111 F.3d at 940 (accord). The United States respectfully requests that, upon a finding of liability, the Court treble any single damages found and impose penalties per claim in the statutory range as appropriate.

* * *

The Court should grant the United States' Motion for Partial Summary Judgment.

Respectfully submitted this 8th day of December, 2020.

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